
CIRM invites public to submit comments and questions for external reviewers

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A group of eight distinguished scientists, ethicists and patient advocates will be reviewing CIRM's performance toward novel stem cell therapies as measured against the goals set forth in the agency's 2006 Strategic Plan [pdf] and the 2009 strategic plan update [pdf].

Prior to the October 13-15 review session, members of the public are invited to submit comments or questions to info@cirm.ca.gov. Please submit these no later than October 8 so they can be forwarded to the reviewers in advance of their meeting.

Please see the schedule for public comment times and location:

The schedule for the meeting is available [here](#).

The following are documents and presentations provided to the reviewers:

- A Brief History, Current Status Report And Options for Next steps [pdf]
 - Alan Trounson Presentation [pdf]
- Report of the Office of the Chairman to External Reviewers [pdf]

The reviewers will be submitting their report prior to the December 8-9 CIRM Governing Board meeting. The document will be posted on the CIRM web site once it is received and it will be discussed in public at the December board meeting. Also at that meeting, topics raised in submitted public comments will be addressed. Members of the public are welcome to attend the December board meeting and comment on the report.

CIRM External Reviewer Biographies:

- Dr. Alan Bernstein (Chair)
- Dr. George Daley
- Professor Sir Martin Evans
- Dr. Igor Gonda
- Dr. Judy Illes
- Dr. Richard A. Insel
- Dr. Richard Klausner
- Dr. Nancy Wexler

Alan Bernstein (chair)

Dr. Alan Bernstein is the inaugural executive director of the Global HIV Vaccine Enterprise, an international alliance of researchers, funders and advocates committed to accelerating the development of an HIV vaccine. The Global HIV Vaccine Enterprise is charged by its founders with setting scientific priorities, mobilizing resources, and improving collaboration in the HIV vaccine field. Originally proposed by 24 leading HIV vaccine researchers in 2003, the Enterprise has to date mobilized more than US\$750 million in support of its scientific plan.

Dr. Bernstein was previously the founding president of the Canadian Institutes of Health Research (CIHR). During his seven years there, he built CIHR into one of the world's leading research agencies, supporting more than 11,000 health researchers with an annual budget of US\$1 billion.

Dr. Bernstein received his Ph.D. in Medical Biophysics at the University of Toronto. Following postdoctoral work in London where he first began working on retroviruses, he returned to Canada to join the faculty of the Ontario Cancer Institute. He later served as head of the Division of Molecular and Developmental Biology at the Samuel Lunenfeld Research Institute at Mount Sinai Hospital, and then its

director of research.

Author of over 200 peer-reviewed scientific publications, Dr. Bernstein is an internationally renowned researcher who has made extensive contributions to the study of embryonic development, stem cells, hematopoiesis and cancer. Dr. Bernstein has received numerous awards for his research and contributions to science, including the McLaughlin Medal of the Royal Society of Canada, the Robert L. Noble Prize from the National Cancer Institute of Canada, the Genetics Society of Canada Award of Excellence, the 2001 Australian Society of Medical Research Medal, an honorary degree from Dalhousie University, the 2007 Medaille du merite from the Institut de Recherche Clinique de Montreal, and the Order of Canada in 2002. Dr. Bernstein chairs and sits on a number of review boards and advisory committees in Canada, the US, the UK, Singapore, and Australia.

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George Daley

Dr. George Daley is director of Stem Cell Transplantation at the Children's Hospital and Dana Farber Cancer Institute, The Samuel E. Lux IV Chair in Hematology, and associate professor of Biological Chemistry and Molecular Pharmacology at Harvard Medical School. Dr. Daley's lab was among the first to produce human induced pluripotent stem cells and diseasespecific stem cells. As a clinician-scientist, Dr. Daley has extensive experience in translating promising science into novel therapeutics. Dr. Daley is the chair of the Scientific Advisory Board of iPerian.

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Sir Martin Evans

Professor Sir Martin Evans Nobel Laureate, Director of the School of Biosciences and Professor of Mammalian Genetics of Cardiff University.

Winner of the Nobel Prize for Medicine, Professor Sir Martin Evans gained his BA in Biochemistry from Christ College, University of Cambridge in 1963. He received an MA in 1966 and a DSc in 1996. In 1969 he was awarded a PhD degree from University College, London.

After graduating from Cambridge, he decided on a career studying the genetic control of vertebrate development. His early PhD research led him to explore the use of cultures of mouse teratocarcinoma stem cells in tissue culture systems. He was the first to maintain these cells in tissue culture under conditions where their ability to differentiate was retained indefinitely.

It was not until 1981, after his return to Cambridge, that he was able to isolate similar cells from normal mouse embryos. Subsequently he and his colleagues demonstrated that these cells which became known as "Embryonic Stem Cells" (ES cells) were able to be used to fully regenerate fertile breeding mice from the tissue culture cells and that these could therefore carry mutations introduced and selected or screened for in culture. This is now the basis of all mouse knockout and targeted genetic manipulation.

These fundamental developments created new routes to experimental mammalian genetics and hence functional genomics. Since then, Sir Martin, who came to Cardiff University's School of Biosciences in 1999, has been exploiting gene knockout and gene trap methods both for novel discovery and to create animal models of human disease. From his laboratory came the first demonstration of gene therapy to cure the deficit in Cystic Fibrosis in a whole animal and recently, from a mutated mouse model, insights into the breast cancer gene BRCA2 function.

Sir Martin has published more than 120 scientific papers. He was elected a Fellow of the Royal Society in 1993 and is a founder Fellow of the Academy of Medical Sciences. In 1993 he was awarded the Walter Cottman Fellowship and the William Bate Hardy Prizes. He was awarded the prestigious Albert Lasker Award for Basic Medical Research in the US in 2001. In 2002 he was awarded an honorary doctorate from Mount Sinai School of Medicine in New York, regarded as one of the world's foremost centres for medical and scientific training.

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Igor Gonda

Dr. Igor Gonda is the Chief Executive Officer of Aradigm Corporation, a public pharmaceutical company in California specializing in the prevention and treatment of severe respiratory diseases. Dr. Gonda was in the past the Chief Scientific Officer at Aradigm and the Chairman of its Scientific Advisory Board. His other industrial appointments included Chief

Executive Officer of Acrux Ltd (Melbourne, Australia); while Senior Scientist/Group Leader at Genentech Inc. (South San Francisco), he was a member of the Core Team that lead the development of the first inhaled recombinant human protein that is now used by many

thousands of cystic fibrosis patients.

Dr. Gonda received his PhD on molecular machines in 1974 from Leeds University (UK). He held various academic positions in the UK, Australia and USA, published over 100 scientific papers and has numerous patents in the fields of biotech and pharmaceutical drugs and delivery systems. He received the Astra Zeneca Industrial Achievement Award of the British Pharmaceutical Society in 2001 and The Thomas T. Mercer Joint Prize of the International Society for Aerosols in Medicine and the American Association for Aerosol Research, for Excellence in Pharmaceutical Aerosols and Inhalable Materials in 2004.

Dr. Gonda has extensive experience with FDA and other regulatory and pharmaceutical compendial authorities: he was member of the 'Ad Hoc' Committee on Standards for Aerosol Inhalations - British Pharmacopoeia Commission, and the Working Party on Metered Dose Aerosols - Australian Drug Evaluation Committee. Dr. Gonda held the office of the President of the Australasian Pharmaceutical Science Association, and board member of the International Society for Aerosols in Medicine. He was also the founding director of the International Pharmaceutical Aerosol Consortium - Regulatory Science and was a member of the Australian Stock Exchange/Ausbiotech working group for the development of the Code of Best Practice of Reporting by Life Science Companies.
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Judy Illes

Dr. Judy Illes is Professor of Neurology and Canada Research Chair in Neuroethics at the University of British Columbia. She is Director of the National Core for Neuroethics at UBC, and faculty in the Brain Research Centre at UBC and at the Vancouver Coastal Health Research Institute. She also holds affiliate faculty appointments in the School of Population and Public Health and the School of Journalism at UBC, and in the Department of Computer Science and Engineering at the University of Washington in Seattle, WA. USA.

Dr. Illes' research focuses on ethical, legal, social and policy challenges specifically at the intersection of the neurosciences and biomedical ethics. This includes studies on stem cells and regenerative medicine, functional neuroimaging in basic and clinical research, dementia, addiction, neurodevelopmental disorders and the commercialization of cognitive neuroscience. She also leads a robust program of research and outreach devoted to improving the literacy of neuroscience and engaging stakeholders on a global scale. Dr. Illes is an internationally recognized author, lecturer, and mentor. She is a co-founder and Executive Committee Member of the Neuroethics Society, a member of the Dana Alliance for Brain Initiatives, and a former member of the Internal Advisory Board for the Institute of Neurosciences, Mental Health and Addiction (CIHR) and of the Forum on Neuroscience and Neurological Disorders of the Institute of Medicine (IoM). Dr. Illes is the author of more than 200 papers, book chapters, essays and editorials. Her most recent book Oxford Handbook of Neuroethics (J. Illes and B.J. Sahakian, Eds., Oxford University Press) is forthcoming in 2011. Dr. Illes is also currently Chair of the Committee on Women in World Neuroscience (WWN) for the International Brain Research Organization (IBRO), and a Canadian representative to the National Academy of Sciences/IBRO US-Canada Committee.
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Richard A. Insel

Dr. Richard Insel is Chief Scientific Officer of Research for the Juvenile Diabetes Research Foundation, where he has responsibility for heading up the strategic direction and oversight of all JDRF research projects.

Dr. Insel has had a distinguished medical and research career in pediatric immunology. Prior to joining JDRF in 2003, he held various leadership positions at the University of Rochester Medical Center during a 26-year tenure there. Dr. Insel was the founding director of the Center for Human Genetics and Molecular Pediatric Disease and a member of the departments of pediatrics and microbiology & immunology. Among other responsibilities, Dr. Insel served as Acting Chair of Pediatrics; Professor of Pediatrics, Microbiology & Immunology, and the Cancer Center; Associate Chair for Pediatric Research; Director of the Strong Children's Research Center; and Chief of the Division of Pediatric Immunology, Allergy and Rheumatology.

Dr. Insel was the scientific co-founder of Praxis Biologics, a biotechnology company established in 1983 and subsequently acquired by Wyeth, the global pharmaceutical and health care products company. Praxis Biologics was responsible for bringing a new vaccine to market that resulted in the virtual elimination of the most common form of childhood meningitis among American infants and children.

Dr. Insel has served on the National Advisory Allergy and Infectious Diseases Council of the National Institutes of Health. He has been a Visiting Associate Professor of Biochemistry and Biophysics at Columbia University's College of Physicians and Surgeons, a fellow in pediatrics (research) at Harvard Medical School, and a fellow in medicine (immunology) at Children's Hospital Medical Center in Boston. He also served in the Laboratory of Parasitic Immunochemistry at the Centers for Disease Control in Atlanta.
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Richard Klausner

Dr. Richard Klausner was formerly the global health executive director of the Bill and Melinda Gates Foundation's Global Health program, whose overarching goal is to improve global health equity. Dr. Klausner previously served as director of the National Cancer Institute (NCI), where he led one of the world's largest research and health agencies, creating successful national and international programs aimed at applying science and technology to improving the public health. In addition, Dr Klausner is currently engaged as an independent consultant for biotech and global health and is a managing director of The Column Group, a strategy-based venture fund.

Dr. Klausner is well known for his work in cell and molecular biology. Dr. Klausner has served as chief of the cell biology and metabolism branch of the National Institute of Child Health and Human Development. He has served on numerous advisory committees and is the past president of the American Society for Clinical Investigation. He is the author of more than 300 scientific articles and several books, and has received numerous awards and honors. Dr. Klausner has served as a senior fellow at the National Academies of Science, advisor to the presidents of the Academies for counter-terrorism, and liaison to the White House Office of Science and Technology Policy. In addition, Dr. Klausner leads the efforts of the National Academies of Science to write standards for science education for the United States. He is a member of the National Academy of Sciences and the Institute of Medicine and the American Academy of Arts and Sciences.

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Nancy Wexler

Dr. Nancy Wexler is the Higgins Professor of Neuropsychology in the Departments of Neurology and Psychiatry of the College of Physicians and Surgeons at Columbia University, as well as the President of the Hereditary Disease Foundation. Involved in public policy, individual counseling, genetic research, and federal health administration, she is most widely known for her important scientific contribution on Huntington's disease. A 20-year study of the world's largest

family with Huntington's disease, in Venezuela, developing a pedigree of over 18,000 individuals and collecting over 4,000 blood samples helped lead to the identification of the Huntington's disease gene at the tip of human chromosome 4. These same blood samples have assisted in the mapping of other disease genes, including those responsible for familial Alzheimer's disease, kidney cancer, two kinds of neurofibromatosis, Amyotrophic Lateral Sclerosis(ALS), dwarfism and others. One result of this work was the development of a presymptomatic test which could tell who is carrying the fatal gene prior to the onset of symptoms.

Wexler received an A.B. from Radcliffe in 1967 and a Ph.D. in clinical psychology from the University of Michigan in 1974. She currently holds or has held numerous public policy positions, including Chair of the Joint NIH/DOE Ethical, Legal and Social Issues Working Group of the National Center for Human Genome Research, Chair of the Human Genome Organization (HUGO) and Member of the Institute of Medicine. Wexler has served as a member of the board of directors of the American Association for the Advancement of Science and on the Advisory Committee on Research on Women's Health, NIH. She has received numerous honors and awards, including several honorary doctorates. Dr. Wexler was recently elected to be a Fellow at the Royal College of Physicians; a Member of the American Academy of Arts and Sciences; a Fellow at the American Association for the Advancement of Science, Section on Neuroscience; a Member of the European Academy of Sciences and Arts; and to the position of Councilor, Society for Neuroscience. She is an honorary Fellow of the New York Academy of Sciences and a Member of the Institute of Medicine, National Academy of Sciences. In 1993, she received the Albert Lasker Public Service Award.

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